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02-09-04



Patent Docket P1150R2C2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Avi J. Ashkenazi et al. Serial No.: 10/713,391 Filed: November 14, 2003 For: DNA 19355 Polypeptide, A Tumor Necrosis Factor Homolog	Group Art Unit: to be assigned Examiner: to be assigned Confirmation No: to be assigned Customer No: 09157 CERTIFICATE OF MAILING Express Mail Number: <u>EV 351 931 975 US</u> <small>I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria Virginia 22313-1450".</small> February <u>5</u> , 2004  Mona Beltran
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TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 with 2 references;
3. Return postcard.

In the event any additional fees are due in connection with the filing of these documents, the Commissioner is authorized to charge such fees to our Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: February 5, 2004

By:



Diane L. Marschang

Reg. No. 35,600

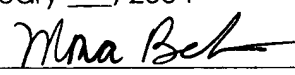
Telephone No. (650) 225-5416

#148905



Patent Docket P1150R2C2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Avi J. Ashkenazi et al. Serial No.: 10/713,391 Filed: November 14, 2003 For: DNA 19355 Polypeptide, A Tumor Necrosis Factor Homolog	Group Art Unit: to be assigned Examiner: to be assigned Confirmation No: to be assigned CUSTOMER NO: 09157 CERTIFICATE OF EXPRESS MAILING Express Mail Number: <u>EV 351 931 975 US</u> <small>I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria Virginia 22313-1450".</small> February <u>5</u> , 2004  Mona Beltran
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

[X] 37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

- ☐ **37 CFR § 1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR § 1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR § 1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR § 1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of item numbers 2 and 4 on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 10/080,455, filed February 22, 2002 and relied upon in this application for an earlier filing date under 35 USC § 120.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not

be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: February 5, 2004

By:

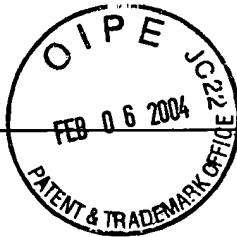
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FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1150R2C2

Serial No.

10/713,391

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Ashkenazi et al.

Filing Date

14 Nov 2003

Group

to be assigned

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	2002/0099198	25.07.02	Yu et al.			
	2	2002/0168729	14.11.02	Yu et al.			
	* 3	5,998,171	07.12.99	Yu et al.			
	4	6,521,742	18.02.03	Yu et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	* 5	307,247	15.03.89	EPO			
	* 6	417,563	20.03.91	EPO (ENGLISH ABSTRACT ATTACHED)			
	* 7	WO 97/01633	16.01.97	PCT			
	* 8	WO 98/06842	19.02.98	PCT			
	* 9	WO 98/07880	26.02.98	PCT			

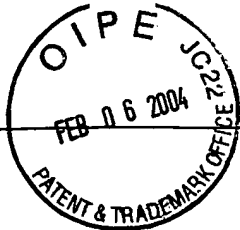
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	* 10	Aggarwal et al., "Tumor Necrosis Factors: Development During the Last Decade" <u>Eur. Cytokine Netw.</u> 7(2):93-124 (April- Ju 1996)					
	* 11	Amakawa et al., "The Hodgkin Disease Antigen CD30 is Crucial for Antigen-Induced Death of Developing T Cells" <u>Symposium on Programmed Cell Death</u> (Abstract No. 10), Cold Spring Harbor Laboratory (1995)					
	* 12	Armitage et al., "Molecular and Biological Characterization of a Murine Ligand for CD40." <u>Nature</u> 357(6373):80-82 (1992)					
	* 13	Ashkenazi et al., "Protection Against Endotoxic Shock by a Tumor Necrosis Factor Receptor Immunoaderisin" <u>Proc. Natl. Acad. Sci.</u> 88:10535-10539 (1991)					
	* 14	Baeuerle et al., "Function and activation of NF-kappa B in the immune system" <u>Ann. Rev. Immunol.</u> 12:141-179 (1994)					
	* 15	Baldwin, A., "The NF-kB and IKB Proteins: New Discoveries and Insights" <u>Ann. Rev. Immunol.</u> 14:649-683 (1996)					
	* 16	Banner et al., "Crystal Structure of the Soluble Human 55 kd TNF Receptor-Human TNF β Complex: Implications for TNF Receptor Activation" <u>Cell</u> 73:431-445 (1993)					
	* 17	Barr and Tomei, "Apoptosis and Its Role in Human Disease" <u>Bio/Technology</u> 12:487-493 (1994)					
	* 18	Baum et al., "Molecular characterization of murine and human OX40/OX40 ligand systems: identification of a human OX40 ligand as the HTLV-1-regulated protein gp34" <u>EMBO Journal</u> 13(17):3992-4001 (1994)					
	* 19	Bodmer et al., "TRAMP, A Novel Apoptosis-Mediating Receptor with Sequence Homology to Tumor Necrosis Factor Receptor 1 and Fas(Apo-1/CD95)." <u>Immunity</u> 6:79-88 (1997)					
	* 20	Boldin et al., "Involvement of MACH, a Novel MORT1/FADD-Interacting Protease, in Fas/APO-1- and TNF Receptor-Induced Cell Death" <u>Cell</u> 85:803-815 (1996)					
	* 21	Boldin et al., "Self-Association of the "Death Domains" of the p55 Tumor Necrosis Factor (TNF) Receptor and Fas/APO1 Prompts Signaling for TNF and Fas/APO1 Effects" <u>Journal of Biological Chemistry</u> 270:387-391 (1995)					

Examiner

Date Considered

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(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

* 22	Brockhaus et al., "Identification of Two Types of Tumor Necrosis Factor Receptors on Human Cell Lines by Monoclonal Antibodies." <u>Proc. Natl. Acad. Sci. USA</u> 87:3127-3131 (1990)
* 23	Brojatsch et al., "CARL, A TNFR-Related Protein, Is a Cellular Receptor for Cytopathic Avian Leukosis-Sarcoma Viruses and Mediates Apoptosis." <u>Cell</u> 87:845-855 (1996)
* 24	Browning et al., "Lymphotoxin β , a Novel Member of the TNF Family That Forms a Heteromeric Complex with Lymphotoxin on the Cell Surface" <u>Cell</u> 72:847-856 (1993)
* 25	Chinnaiyan and Dixit, "The Cell-Death Machine" <u>Current Biology</u> 6:555-562 (1996)
* 26	Chinnaiyan et al., "FADD, a novel death domain-containing protein, interacts with the death domain of Fas and initiates apoptosis" <u>Cell</u> 81:505-512 (1995)
* 27	Chinnaiyan et al., "FADD/MORT1 Is a Common Mediator of CD95 (Fas/APO-1) and Tumor Necrosis Factor Receptor-induced Apoptosis" <u>Journal of Biological Chemistry</u> 271:4961-4965 (1996)
* 28	Chinnaiyan et al., "Interaction of CED-4 with CED-3 and CED-9: A Molecular Framework for Cell Death" <u>Science</u> 275:1122-1126 (1997)
* 29	Chinnaiyan et al., "Signal Transduction by DR3, A Death Domain-Containing Receptor Related to TNFR-1 and CD95." <u>Science</u> 274:990-992 (1996)
* 30	Cleveland and Ihle, "Contenders in FasL/TNF Death Signaling" <u>Cell</u> 81:479-482 (1995)
* 31	Dealtry et al., "DNA Fragmentation and Cytotoxicity Caused by Tumor Necrosis Factor is Enhanced by Interferon- γ " <u>European Journal of Immunology</u> 17:689-693 (1987)
* 32	Degli-Esposti et al., "Cloning and Characterization of TRAIL-R3, a Novel Member of the Emerging TRAIL Receptor Family" <u>Journal of Experimental Medicine</u> 186(7):1165-1170 (1997)
* 33	Eck and Sprang, "The structure of tumor necrosis factor- α at 2.6 Å resolution" <u>Journal of Biological Chemistry</u> 264(29):17595-17605 (1989)
* 34	Enari et al., "Involvement of an ICE-like protease in Fas-mediated Apoptosis" <u>Nature</u> 375:78-81 (1995)
* 35	Fraser and Evan, "A License to Kill" <u>Cell</u> 85:781-784 (1996)
* 36	Gelb et al., "Pycnodysostosis: Refined Linkage and Radiation Hybrid Analyses Reduce the Critical Region to 2 cM at 1q21 and Map Two Candidate Genes" <u>Human Genet.</u> 98:141-144 (1996)
* 37	Goding, "Production of Monoclonal Antibodies" <u>Monoclonal Antibodies: Principles and Practice</u> , Academic Press, pps. 59-103 (1986)
* 38	Goodwin et al., "Molecular Cloning and Expression of the Type 1 and Type 2 Murine Receptors for Tumor Necrosis Factor." <u>Mol. Cell. Bio.</u> 11:3020-3026 (1991)
* 39	Gruss and Dower, "Tumor Necrosis Factor Ligand Superfamily: Involvement in the Pathology of Malignant Lymphomas" <u>Blood</u> 85:3378-3404 (1995)
* 40	Gruss, H.J. et al., "Molecular, structural, and biological characteristics of the tumor necrosis factor ligand superfamily" <u>Int. J. Clin. Lab. Res</u> 26(3):143-159 (1996)
* 41	Hale et al., "Demonstration of In Vitro and In Vivo Efficacy of Two Biologically Active Human Soluble TNF Receptors Expressed in E. coli." <u>J. Cell. Biochem.</u> (abstract only, suppl. 15F; P 424) pps. 113 (1991)

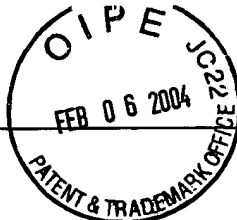
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FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1150R2C2	Serial No. 10/713,391
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Ashkenazi et al.	
				Filing Date 14 Nov 2003	Group to be assigned
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
* 42	Hohmann et al., "Two different cell types have different major receptors for human tumor necrosis factor (TNF α)" <u>Journal of Biological Chemistry</u> 264(25):14927-14934 (1989)				
* 43	Hsu et al., "TRADD-TRAF2 and TRADD-FADD interactions define two distinct TNF receptor 1 signal transduction pathways" <u>Cell</u> 84:299-308 (1996)				
* 44	Itoh et al., "The Polypeptide Encoded by the cDNA for Human Cell Surface Antigen Fas Can Mediate Apoptosis." <u>Cell</u> 66:233-243 (1991)				
* 45	Johnson et al., "Expression and Structure of the Human NGF Receptor" <u>Cell</u> 47:545-554 (1986)				
* 46	Kitson et al., "A Death-Domain-Containing Receptor that Mediates Apoptosis" <u>Nature</u> 384:372-375 (1996)				
* 47	Klein et al., "Selection for Genes Encoding Secreted Proteins and Receptors" <u>Proc. Natl. Acad. Sci. USA</u> 93(14):7108-7113 (1996)				
* 48	Kohno et al., "A Second Tumor Necrosis Factor Receptor Gene Product Can Shed a Naturally Occurring Tumor Necrosis Factor Inhibitor." <u>Proc. Natl. Acad. Sci. USA</u> 87:8331-8335 (1990)				
* 49	Kozak, "An analysis of vertebrate mRNA sequences: intimations of translational control" <u>Journal of Cell Biology</u> 115:887-903 (1991)				
* 50	Krammer et al., "Regulation of Apoptosis in the Immune System" <u>Curr. Op. Immunol.</u> 6:279-289 (1994)				
* 51	Lewis et al., "Cloning and Expression of cDNAs for Two Distinct Murine Tumor Necrosis Factor Receptors Demonstrate One Receptor is Species Specific." <u>PNAS USA</u> 88:2830-2834 (1991)				
* 52	Lewit-Bentley et al., "Structure of tumour necrosis factor by X-ray solution scattering and preliminary studies by single crystal X-ray diffraction" <u>J. Mol. Biol.</u> 199(2):389-392 (1988)				
* 53	Loetscher et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor" <u>Cell</u> 61:351-359 (1990)				
* 54	MacFarlane et al., "Identification and Molecular Cloning of Two Novel Receptors for the Cytotoxic Ligand TRAIL" <u>Journal of Biological Chemistry</u> 272(41):25417-25420 (1997)				
* 55	MacKay et al., "Differential Responses of Fibroblasts from Wild-Type and TNF-R55-Deficient Mice to Mouse and Human TNF- α Activation" <u>J. Immunol.</u> 153:5274-5284 (1994)				
* 56	Malinin et al., "MAP3K-related kinase involved in NF- κ B induction by TNF, CD95 and IL-1" <u>Nature</u> 385(6616):540-544 (February 6, 1997)				
* 57	Mallett et al., "Characterization of the MRC OX40 Antigen of Activated CD4 Positive T Lymphocytes - A Molecule Related to Nerve Growth Factor Receptor" <u>EMBO Journal</u> 9(4):1063-1068 (April 1990)				
* 58	Marsters et al., "Activation of Apoptosis by Apo-2 Ligand is Independent of FADD but Blocked by CrmA." <u>Current Biology</u> 6(6):750-752 (1996)				
* 59	Marsters et al., "Apo-3, A New Member of the Tumor Necrosis Factor Receptor Family, Contains a Death Domain and Activates Apoptosis and NF- κ B." <u>Curr. Biol.</u> 6(12):1669-1676 (1996)				
* 60	Marsters et al., "Herpesvirus Entry Mediator, A Member of the Tumor Necrosis Factor Receptor (TNFR) Family, Interacts with Members of the TNFR-Associated Factor Family and Activates the Transcription Factors NF- κ B and AP-1." <u>J. Bio. Chem.</u> 272(22):14029-14032 (1997)				
* 61	Marsters et al., "Interferon γ Signals Via a High-Affinity Multisubunit Receptor Complex That Contains Two Types of Polypeptide Chain" <u>Proc. Natl. Acad. Sci. USA</u> 92:5401-5405 (1995)				
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LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

* 62	Montgomery et al., "Herpes Simplex Virus-1 Entry into Cells Mediated by a Novel Member of the TNF/NGF Receptor Family" <u>Cell</u> 87(3):427-436 (1996)
* 63	Muzio et al., "FLICE, A Novel FADD-Homologous ICE/CED-3-like Protease, Is Recruited to the CD95 (Fas/APO-1) Death-Inducing Signaling Complex" <u>Cell</u> 85:817-827 (1996)
* 64	Nagata and Golstein, "The Fas Death Factor" <u>Science</u> 267:1449-1456 (1995)
* 65	Nagata, S., "Apoptosis by Death Factor." <u>Cell</u> 88:355-365 (Feb 1997)
* 66	Nocentini et al., "A New Member of the Tumor Necrosis Factor/Nerve Growth Factor Receptor Family Inhibits T Cell Receptor-Induced Apoptosis." <u>Proc. Natl. Acad. Sci.</u> 94(12):6216-6221 (1997)
* 67	Nophar et al., "Soluble Forms of Tumor Necrosis Factor Receptors (TNF-Rs). The cDNA for the Type I TNF-R, Cloned Using Amino Acid Sequence Data of its Soluble Form, Encodes Both the Cell Surface and a Soluble Form of the Receptor." <u>EMBO Journal</u> 9:3269-3278 (1990)
* 68	O'Reilly et al. <u>Baculovirus Expression Vectors: A Laboratory Manual</u> , Oxford:Oxford University Press (1994)
* 69	Pan et al., "An Antagonist Decoy Receptor and a Death-Domain Containing Receptor for TRAIL." <u>Science</u> 277:815-818 (Aug 1997)
* 70	Pan et al., "The Receptor for the Cytotoxic Ligand TRAIL." <u>Science</u> 276:111-113 (Apr 4, 1997)
* 71	Peetre et al., "A tumor necrosis factor binding protein is present in human biological fluids" <u>European Journal of Haematology</u> 41:414-419 (1988)
* 72	Pitti et al., "Induction of Apoptosis by Apo-2 Ligand, a New Member of the Tumor Necrosis Factor Cytokine Family" <u>Journal of Biological Chemistry</u> 271:12687-12690 (1996)
* 73	Radeke et al., "Gene Transfer and Molecular Cloning of the Rat Nerve Growth Factor Receptor." <u>Nature</u> 325:593-597 (1987)
* 74	Raff, "Social Controls on Cell Survival and Cell Death" <u>Nature</u> 356:397-400 (1992)
* 75	Ray et al., "Viral Inhibition of Inflammation: Cowpox Virus Encodes an Inhibitor of the Interleukin-1 β Converting Enzyme" <u>Cell</u> 69:597-604 (May 15, 1992)
* 76	Ruppert et al., "Cloning and Expression of Human TAF _{II} 250: a TBP-associated Factor Implicated in Cell-cycle Regulation" <u>Nature</u> 362:175-179 (1993)
* 77	Sachs et al., "Control of Programmed Cell Death in Normal and Leukemic Cells: New Implications for Therapy" <u>Blood</u> 82:15-21 (1993)
* 78	Sambrook et al. <u>Molecular Cloning: A Laboratory Manual</u> , Second edition, New York: Cold Spring Harbor Laboratory Press (1989)
* 79	Schall et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor" <u>Cell</u> 61:361-370 (1990)
* 80	Schmid et al., "DNA Fragmentation: Manifestation of Target Cell Destruct. Mediated by Cytotoxic T-cell Lines, Lymphotoxin-Secreting Helper T-cell Clones, and Cell-Free Lymphotoxin-Containing Supernatant." <u>PNAS USA</u> 83:1881-1885 (1986)
* 81	Seckinger et al., "Purification and biologic characterization of a specific tumor necrosis factor α Inhibitor" <u>Journal of Biological Chemistry</u> 264:11966-11973 (1989)

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